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BROWDY AND NEIMARK  
419 SEVENTH STREET N W  
WASHINGTON DC 20004

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EXAMINER	
SCHWADRON, R	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/06/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

# Office Action Summary

Application No.  
**08/485,129**

Applicant(s)  
**Wallach et al.**

Examiner  
**Ron Schwadron, Ph.D.**

Group Art Unit  
**1644**



☒ Responsive to communication(s) filed on Apr 3, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 11-14 and 34-50 is/are pending in the application.

Of the above, claim(s) 14, 39, 42, 45, and 50 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 11-13, 34-38, 40, 41, 43, 44, and 46-49 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

15. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's submission after final filed on 4/3/98 has been entered. The amendments filed 3/31/98 and 11/6/97 have already been entered.

16. Newly submitted claim 50 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The previous elected invention is drawn to DNA, expression vectors containing said DNA, and host cells containing said expression vectors, classified in Class 435, subclasses 320.1, 240.2 and 252.3, and Class 536, subclass 23.5. The invention of claim 50 is drawn to a process for producing a protein, classified in Class 435, subclass 69.1. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as preparation of DNA probes that can be used in hybridization assays to detect TBP-II DNA in cells. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II and Groups I and II have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 50 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

17. Claims 11-13,34-38,40,41,43,44,46-49 are under consideration. Claims 11 and 37 have been amended. Claims 46-49 are newly added.

18. Claims 11-13,34,40,41,46-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "including the amino acid sequence: Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr" in claims 11 or 46. The specification discloses that said sequence was determined by "N-terminal sequence analysis" (eg. see page 23). This indicates that said sequence is in the N-terminal region of the TBP-II molecule recited in the claim. The sequence as recited in the claims under consideration encompasses molecules wherein said sequence is not at the N-terminal (eg. is found in middle of molecule or at COOH terminus, etc.). There is no support for a DNA encoding such a molecule in the specification as originally filed. There is no written description of such a molecule in the specification as originally filed (eg. it constitutes new matter).

A preferred substitution uses the language in original claim 6 with regards to the location of the sequence recited in the claim.

19. Claims 11-13,34,40,41,46-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "after being purified by affinity chromatography with TNF- $\alpha$ , elutes from a reversed-phase high pressure liquid chromatography column in a fraction corresponding to about 31% acetonitrile and shows an apparent molecular weight of about 30 kDa when measured by reducing SDS-PAGE." in claims 11 or 46. Regarding applicants comments, the particular passages of the specification/priority document to which applicant refers details a particular set of conditions under which the experiments were performed wherein said language is not recited in the claims. The scope of the claim is not commensurate with the scope of the disclosure of the specification. There is no written description of such a molecule in the specification as originally filed (eg. it constitutes new matter).

Original claim 7 recites language describing the purification procedure that has support in

the specification as originally filed.

20. Claims 35,43,44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the claimed molecules. The specification discloses that the features of the TBP-II molecule recited in claim 35 are found in a molecule of 30kd. However, there is no disclosure in the specification of the existence of a TBP-II molecule recited in claim 35 other than one wherein the molecular weight is 30kd. The scope of the claimed molecule exceeds the scope of the disclosure of the specification as originally filed. There is no written description of such a molecule in the specification as originally filed (eg. it constitutes new matter).

21. Claims 35, 43,44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the claimed molecule. The specification discloses that the features of the TBP-II molecule recited in claim 35 are found in a molecule of 30kd. However, there is no disclosure in the specification of the existence of a TBP-II molecule recited in claim 35 other than one wherein the molecular weight is 30kd. There is no evidence of record that TBP-II with the properties recited in the claim exists except in a 30kd molecule. Therefore, the specification is not enabling for the claimed DNA.

22. Claims 11-13,34-38,40,41,43,44,46-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether

that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . . claimed subject matter", *Vas-Cath, Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed DNAs and molecules containing said DNAs.

The instant claims encompass an isolated DNA molecule or vectors or host cells which contain said DNA wherein said DNA encodes a protein consisting of naturally occurring TBP-II. There is no disclosure in the specification of an intact DNA sequence which encodes said molecule. There is no disclosure in the specification of any DNA sequence which encodes the claimed DNA. The claimed invention encompasses genomic DNA encoding the TBP-II recited in the claims. However, there is no written description of said genomic DNA in the specification (eg. no disclosure as to whether the genomic DNA has introns or where said introns are located, etc.). The claimed DNA encompasses DNA encoding the TBP-II molecule wherein said molecule is derived from species other than humans. However, there is no written description of such DNA sequences in the specification as originally filed. The claimed molecule recites physical features of a TBP-II protein and the amino acid sequences of a 10-13 amino acid sequence of the N terminal of a molecule that contains at least 250 amino acids. There is no disclosure in the specification of any DNA sequence which encodes the claimed molecule. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In *University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, *id.* at 1240. In the instant case, the specification has not provided even a single DNA sequence which encodes the claimed DNA. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . . conception has not been achieved until reduction to practice has occurred", *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of *The*

Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606.

23. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

24. Claims 11-13,46-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite in the recitation of "apparent molecular weight" because it is unclear what this means or encompasses. It is unclear as to what molecular weight is encompassed by the term "apparent molecular weight" and there is no definition of said term in the specification. A preferred substitution is to delete "apparent" and substitute "about" as per original claim 7.

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371<sup>o</sup> of this title before the invention thereof by the applicant for patent.

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26. Claims 11-13,34-38,40,41,43,44,46-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al. (US Patent 5,395,760).

Smith et al. teach the claimed inventions (see Figure 2a and claims). This rejection can be overcome by the submission of English language copies of the foreign priority documents, assuming the claimed inventions are disclosed in said foreign priority documents.

Regarding applicants comments, for the same reasons that the claims under consideration were rejected as containing new matter in this Office Action, the claims do not have priority to the foreign priority documents as cited in the instant application.

27. No claim is allowed.

28. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 305-3014.

29. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Tuesday through Friday from 8:30 to 6:00. The examiner can also be reached on alternative Mondays. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP 1800-1600



Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644

July 2, 1998



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